



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,678	07/07/2003	Alexander D. Romaschin	1148-1-002 CIPF	7389

23565 7590 10/01/2007
KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
----------	--------------

1645

MAIL DATE	DELIVERY MODE
-----------	---------------

10/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,678

Applicant(s)

ROMASCHIN ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4-30-07 and 8-18-06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed 8-18-06 and 4-30-07 have been entered into the record. Claims 1-20 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The objection to claims 8 and 15 because of informalities is withdrawn in view of the amendment to the claims.

The priority issue is resolved in view of the granting of the petition for a late claim of priority.

The objection to the oath or declaration as defective is withdrawn in view of the new declaration.

The amendment filed 7-9-04 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure is resolved by Applicants amendment to the specification.

Rejections Maintained

Claims 1-20 stand rejected under 35 USC 103(a) as being unpatentable over DeBaetselier et al (US Patent NO. 4,737,455) in view of Winkelhake et al (Journal of Infectious Diseases, Vol. 165:26-33, 1992) for reasons of record in the last office action.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that no standard curve relating direct assay readout to analyte level is employed by the inventive assay as is used in the prior art. This is not persuasive, applicants claim language is "open" and such language does not exclude the presence of other steps or reagents. Applicants further argued limitations in the specification are not read into the claims. Applicants argue that the methods can be performed with white

Art Unit: 1645

blood cells endogenously present in the sample or from another source and do not require the hybrid cells of DeBaetselier. This is not persuasive again, Applicants claim language is again open and the argued limitations are not present in the claims. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."); < Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.). Applicants admit that the term "white blood cells" includes hybrid cells as taught by the combination. Applicants further argue that Winkelhake et al does not cure the deficiencies of DeBaestelier. This is again not persuasive because Winkelhake et al provides for the claimed target antigens in sepsis and not the assay method steps. The combination provides for analytes in sepsis and DeBaestelier does not fail for the reasons set forth above.

The rejection is maintained.

Claims 1, 2, 5, 6, 8, 9, 12, 14, 15, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilius et al (Journal of Bioluminescence and Chemiluminescence, 7:117-122, 1992) is maintained for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that there is no reasonable expectation of success for analyte detection by contacting the cognate antibody and that a motivation to make the change and a

Art Unit: 1645

reasonable expectation of success are required for a rejection under 103 to be proper. With respect to motivation, the courts have held "In contrast to the characterization of some commentators, the suggestion test is not a rigid categorical rule. The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). As we explained in *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997), "there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006). Additionally, motivation was provided. With respect to a reasonable expectation of success, the use of antibodies to detect cognate antigen has been in the art for more than 20 years. There are textbooks that provide for the requisite assays and conditions. There is nothing beyond routine ingenuity to provide for conditions allowing the interaction of antigen and its cognate antibody. As such, Applicants arguments are not persuasive. It is obvious to the skilled artisan when having an antigen and antibody cognate pair, that the antigen can be used to detect the antibody and the antibody can be used to detect the antigen. This interaction is a fundamental principle established repeatedly in more than 20 years of immunodiagnostic assays. Therefore, Applicants assertion of no reasonable expectation of success is not persuasive.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilius et al (Journal of Bioluminescence and Chemiluminescence, 7:117-122, 1992) in view of Winkelhake et al (The Journal of Infectious Diseases, 165:26-33, 1992).

Applicants' arguments have been carefully considered. The arguments again address no motivation in the cited art and no reasonable expectation of success. With

Art Unit: 1645

respect to motivation, motivation was provided by the examiner. Further, the courts have held "In contrast to the characterization of some commentators, the suggestion test is not a rigid categorical rule. The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). As we explained in *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997), " there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006). With respect to using whole blood in an immunological assay, whole blood is used in a wide variety of immunodiagnostic assays in the art for over 20 years. (i.e. blood typing) There is no reason to believe that whole blood could not be used as combined. The expectation of success must be reasonable and does not have to be guaranteed.

Status of Claims

Claims 1-20 stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

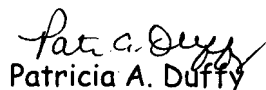
Art Unit: 1645

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Patricia A. Duffy

Primary Examiner

Art Unit 1645